UNC HEALTH	Procedure Name	**Investigational Drug Services Returns and Destruction of IP**
	SOP #	**UNC IDS SOP-08**
	Date this Version Effective	**17 Mar 2021**
	Responsible for Content	**IDS Manager**

I. Description

This SOP describes the process and documentation of returns of investigational product (IP) as well as the process and documentation of the destruction of IP returns and materials used in the dispensing of IP.

II. Rationale

All pharmacy personnel, both at Central IDS and at satellite locations, involved in the handling, preparation, and returns of IP must be aware of procedures and proper documentation of their activities.

The goal of this SOP is to produce consistent practice to ensure compliance.

III. Procedures

A. USP <800> and Hazardous Medications

1. USP <800> establishes practices to protect health care employees from the dangers of repeated and extended exposure to hazardous medications. The standards will be considered to apply to employees as well as to any visitors to IDS who will handle medications that are considered hazardous—monitors, coordinators, and nurses, etc.
2. At the time of protocol review by the assigned lead pharmacist, a determination will be made whether the IP to be handled by IDS will be considered hazardous or not. To make this determination, the lead pharmacist will use any available source they deem relevant, including, but not limited to, guidelines from USP <800>, NIOSH, sponsor-provided guidance, and any institutional hazardous medication lists or policies.
3. If IP is deemed to be hazardous, it will be handled according to the local hazardous medication policies and any federal or state statute or regulation.

B. General Destruction Guidelines

1. All destruction of IP is documented in the electronic accountability system.
2. IDS will not log patient returns into any IRT system. For further detail on the roles of IDS or activities that IDS does not perform, please see UNC IDS SOP-01.
3. Controlled substances are exempted from this SOP. For guidance on the handling of controlled substances by IDS, see UNC IDS SOP-16.

C. Destruction of IP

1. All IP is placed into black Resource Conservation and Recovery Act (RCRA) pharmaceutical waste bins located in each pharmacy. These are then collected by local environmental health and safety staff for destruction.
2. After collection, IP is shipped to an incinerator where it is incinerated for final destruction.

3. Supplies, PPE, and other materials used in the preparation of IP or dispensing of IP are placed into red hazardous waste bags. These bags are collected by local environmental health and safety staff for destruction. These items may either be incinerated for final destruction or autoclaved prior to wasting.

D. IP Containers After Use

1. Immediately after use to prepare IP for dispensing, any containers, vials, boxes, or other empty or partially used containers will be disposed of in the appropriate waste streams.
2. Any containers storing oral IP with remaining dosage units to be dispensed at a later time will be retained until all dosage units have been dispensed and the container is empty. Once emptied, oral dosage containers will be disposed of in the appropriate waste stream.
3. Separate or duplicate records of destruction outside of our electronic accountability system will not be maintained for any partially used or fully emptied vials used during the preparation and dispensing of IP.
4. Any IV bags, syringes, filter sets, infusion lines, patches, topical products, or other materials used in the process of administering prepared doses of IP to patients will be considered hazardous waste and will be immediately disposed of into the appropriate waste stream.

E. Oral, Topical, Transdermal IP Returns

1. Study coordinators will perform a count of the product to be returned and provide documentation of their count to IDS. IDS staff will then perform a second, blind count of the returned product.
2. If both counts are in agreement, returns will be destroyed by being placed into the appropriate waste stream. Returns will be considered destroyed at the time of placement into waste bins.
3. If counts are discrepant, IDS will work with the coordinator to resolve the discrepancy and document any relevant information. If the discrepancy can be resolved, the final count will be documented and returns will be destroyed as described in section C above.
4. IP returned to the pharmacy by the study coordinator will be accounted for in the electronic accountability system. Aside from documentation provided by study coordinators and data in the electronic accountability system, no other documentation of returns will be maintained.
5. If a study wishes to request that returns be retained for monitor review, it is the responsibility of the study team, sponsor, or the monitor to notify IDS prior to study opening. IDS will keep returns for monitor review for an additional fee, if approved, at the discretion of the IDS manager. Maintenance of returns for monitor review will only be approved if required by law/regulation or if a compelling argument for the need to maintain returns is made (again, at the discretion of the IDS manager).
6. If returns are kept, they will only be kept for 90 calendar days or until the next monitoring visit, whichever is sooner, and then they must be accounted for and destroyed or sent back to the sponsor. If a monitor neglects to appropriately destroy or send any returns to the study sponsor at a monitor visit, IDS will destroy any and all returns for the applicable protocol(s) within 30 calendar days of monitor visit.
7. Hazardous drug returns will be immediately destroyed after accounting for their return in the electronic accountability system. Under no circumstances will hazardous returns be stored by IDS.
8. Per section D above, no returns of any intravenous, intradermal, topical, or subcutaneous product will be accepted by IDS.

F. Tear-Off Labels

1. IDS will not save tear-off labels from dispensed IP. Sponsors may request that tear-off labels be retained for an additional fee if there is additional information on the tear-off label compared to other sources and at the discretion of the IDS system clinical manager.
2. If tear-off labels are retained with paper dispensing documentation, they will be affixed to the dispensing record and then stored electronically as a part of the dispensing record. The paper record of dispensing nor the tear-off label will be guaranteed to be kept in paper form. (For further information on IDS practices regarding the storage of documents, please see UNC IDS SOP-11 and UNC IDS SOP-10.)

G. Temperature Monitoring Devices Sent to IDS

1. Devices for monitoring the temperature of shipments will be stopped immediately upon opening the shipment, and the data from the monitoring device will be downloaded and saved electronically. (For further information on temperature monitoring devices and procedures for temperature excursions, see UNC IDS SOP-05.)
2. Once temperature data is confirmed to be stored appropriately, the temperature monitoring device will be destroyed. Multi-use monitoring devices that have been requested be returned with shipping containers will be returned.
3. If the temperature monitoring device is not downloadable, then it will be kept until the next monitor visit. At their next visit, the monitor will review the device, remove it from the paper it is affixed to (if this is applicable), replace it with the tear-off label from the temperature monitoring device (if applicable), and then destroy the device. If the monitor neglects to review and destroy the devices which were made available to them at their visit, IDS will destroy them on behalf of the monitor.

H. Quarantined IP

1. IP that has been placed into quarantine will be stored for up to 90 calendar days to allow for a decision to be reached regarding returning the IP to normal stock or wasting the IP.
2. If IP is supplied to IDS, then at the time of quarantine study sponsor will be notified and be requested to investigate and provide instruction for next steps. If a decision is not reached within 90 calendar days, IDS will destroy the IP into the appropriate waste stream.
3. If IP is acquired by IDS, then IDS will communicate with the study coordinator and assist the coordinator in making a determination of how to proceed.
4. All IP received by IDS that is not properly labeled will be immediately quarantined. For proper labeling requirements, please see UNC IDS SOP-13

I. IP Dispensed and Not Picked Up

1. If the IP never left the pharmacy and is not an IRT-assigned product, it may be returned to stock.
2. If IRT-assigned, then it will be accounted for as a subject return. Because no coordinator count will be available in this case, a blind double count will be performed by IDS staff.

J. Expired IP

1. Expired IP will be retained for up to 90 calendar days after expiration or until the next monitor visit, whichever is sooner. Arrangements can be made by the sponsor for expired IP to be retained for longer periods of time at the discretion of the IDS system clinical manager. After 90 calendar days or the agreed upon extension period, expired IP will be destroyed per the waste destruction policies of the local institution.

K. Unused IP at Time of Study Close

1. IP remaining in possession of IDS at time of study closure will be destroyed or returned to the sponsor by the monitor at the study close-out visit.
2. Any IP not destroyed or returned by the monitor at the study close-out visit will be accounted for and destroyed within 30 calendar days.
3. If the study sponsor or monitor neglect to perform a close-out visit within 90 days of study closure with IDS, IDS will destroy all unused IP within 90 days of study closure with IDS.

IV. Original Procedure Date and Revisions

01 Jul 2019 – SOP live.

15 Jun 2020 – Updated period of retention of expired medications. Clarified language to be more specific. Expanded criteria for quarantine to include improperly labeled IP. Clarified the reasons why requests for maintenance of patient returns may or may not be approved. Inserted details for destruction process.

17 Mar 2021 – Simplified language in destruction description to address misunderstanding of practice by IDS.